

E AND R AMENDMENTS TO LB 1022

Introduced by Enrollment and Review Committee: McGill, 26,
Chairperson

1 1. Strike the original sections and all amendments
2 thereto and insert the following new sections:

3 Section 1. Sections 1 to 30 of this act shall be known
4 and may be cited as the Veterinary Drug Distribution Licensing Act.

5 Sec. 2. The purpose of the Veterinary Drug Distribution
6 Licensing Act is to protect the public health, safety, and welfare
7 by providing for the authorization and licensure of facilities and
8 persons to distribute, under specific conditions, veterinary legend
9 drugs to the public in the State of Nebraska.

10 Sec. 3. For purposes of the Veterinary Drug Distribution
11 Licensing Act, the definitions found in sections 4 to 12 of this
12 act shall apply.

13 Sec. 4. Animal means any animal other than man.

14 Sec. 5. Controlled substance has the definition found in
15 section 28-401.

16 Sec. 6. Department means the Division of Public Health of
17 the Department of Health and Human Services.

18 Sec. 7. Distribution means the act of receiving orders,
19 possessing, warehousing, and record keeping relevant to veterinary
20 legend drug sales and delivery. Distribution does not include:
21 (1) Intracompany sales of veterinary legend drugs, including any
22 transaction or transfer between any division, subsidiary, or parent
23 company and an affiliated or related company under common ownership

1 or common control; or (2) the delivery of or the offer to deliver
2 a veterinary legend drug by a common carrier solely in the usual
3 course of business of transporting such drugs as a common carrier
4 if the common carrier does not store, warehouse, or take legal
5 ownership of such drugs.

6 Sec. 8. Human legend drug means any drug labeled for
7 human use and required by federal law or regulation to be dispensed
8 pursuant to a prescription, including finished dosage forms and
9 active ingredients. Human legend drug does not include a device or
10 a device component, part, or accessory.

11 Sec. 9. Veterinarian-client-patient relationship means a
12 relationship pursuant to which (1) a veterinarian has assumed the
13 responsibility for making clinical judgments regarding the health
14 of an animal and the need for medical treatment and the client
15 has agreed to follow the veterinarian's instructions, (2) the
16 veterinarian has sufficient knowledge of the animal to initiate at
17 least a general or preliminary diagnosis of the medical condition
18 of the animal, meaning that the veterinarian has recently seen
19 and is personally acquainted with the keeping and care of the
20 animal by virtue of an examination of the animal or by medically
21 appropriate and timely visits to the premises where the animal is
22 kept, and (3) the veterinarian is readily available or has arranged
23 for emergency coverage and for followup evaluation in the event of
24 adverse reactions or the failure of the treatment regimen.

25 Sec. 10. Veterinary drug distributor means any premises,
26 other than a pharmacy, that holds a valid license issued by
27 the department under the Veterinary Drug Distribution Licensing

1 Act. Veterinary drug distributor includes, but is not limited to,
2 any premises described in a license issued by the department in
3 which veterinary legend drugs are stored, possessed, or warehoused
4 and from which veterinary legend drugs are furnished, sold, or
5 otherwise disseminated pursuant to a veterinary drug order from a
6 veterinarian licensed to practice in Nebraska.

7 Sec. 11. Veterinary drug order means a lawful order or
8 prescription of a veterinarian licensed to practice in this state,
9 which order or prescription is issued pursuant to the establishment
10 of a bona fide veterinarian-client-patient relationship. For
11 purposes of the Veterinary Drug Distribution Licensing Act, a
12 veterinary drug order shall expire and become void one hundred
13 eighty days after the date of issue.

14 Sec. 12. Veterinary legend drug means a drug which under
15 federal law is required, prior to being distributed, to be labeled
16 with the following statement: "Caution: Federal law restricts this
17 drug to use by or on the order of a licensed veterinarian."

18 Sec. 13. No person or entity shall distribute, sell,
19 or offer for sale any veterinary legend drug in this state
20 without first obtaining a license issued by the department under
21 the Veterinary Drug Distribution Licensing Act, except that a
22 veterinarian licensed under the Veterinary Medicine and Surgery
23 Practice Act acting within the scope of practice of his or
24 her profession shall not be required to be licensed under the
25 Veterinary Drug Distribution Licensing Act.

26 Sec. 14. (1) Any person, partnership, corporation,
27 business entity, or other entity located in this state or any other

1 location that acts as a veterinary drug distributor shall obtain
2 a veterinary drug distributor license from the department prior
3 to engaging in distribution of veterinary legend drugs in or into
4 this state.

5 (2) An applicant for an initial or renewal license as a
6 veterinary drug distributor shall file a written application with
7 the department. The application shall be accompanied by the fee
8 established by the department pursuant to section 19 of this act
9 and shall include the following information:

10 (a) The applicant's name, business address, type of
11 business entity, and telephone number. If the applicant is a
12 partnership, the application shall include the name of each partner
13 and the name of the partnership. If the applicant is a corporation,
14 the application shall include the name and title of each corporate
15 officer and director, all corporate names of the applicant, and
16 the applicant's state of incorporation. If the applicant is a sole
17 proprietorship, the application shall include the name of the sole
18 proprietor, the name of the proprietorship, and the proprietor's
19 social security number. The social security number shall not be
20 a public record and may only be used by the department for
21 administrative purposes;

22 (b) All trade or business names used by the applicant;

23 (c) The addresses and telephone numbers of all facilities
24 to be used by the applicant for the storage, handling, and
25 distribution of veterinary legend drugs and the names of persons
26 to be in charge of such facilities. A separate license shall be
27 obtained for each such facility;

1 (d) A listing of all licenses, permits, or other
2 similar documentation issued to the applicant in any other state
3 authorizing the applicant to purchase, possess, and distribute
4 veterinary legend drugs;

5 (e) The names and addresses of the owner of the
6 applicant's veterinary legend drug distribution facilities, a
7 designated manager at each such facility, and all managerial
8 employees at each such facility; and

9 (f) Other information as required by the department,
10 including affirmative evidence of the applicant's ability to comply
11 with the Veterinary Drug Distribution Licensing Act and the rules
12 and regulations adopted under the act.

13 (3) The application shall be signed by:

14 (a) The owner, if the applicant is an individual or
15 partnership;

16 (b) The member, if the applicant is a limited liability
17 company with only one member, or two of its members, if the
18 applicant is a limited liability company with two or more members;
19 or

20 (c) Two of its officers, if the applicant is a
21 corporation.

22 (4) A veterinary drug distributor holding a valid license
23 issued pursuant to the Veterinary Drug Distribution Licensing Act
24 shall have the authority to purchase, possess, or otherwise acquire
25 veterinary legend drugs.

26 Sec. 15. A veterinary drug distributor shall establish,
27 maintain, and adhere to written policies and procedures for

1 the receipt, storage, security, inventory, and distribution of
2 veterinary legend drugs, including policies and procedures for
3 identifying, recording, and reporting destruction, losses, or
4 thefts of veterinary legend drugs and for correcting all errors and
5 inaccuracies in inventories. The policies shall contain a provision
6 for annual review at which time the policies shall be updated
7 as necessary. A record documenting the review shall be kept with
8 the policies and procedures and shall indicate the date of the
9 review and the signature of the designated representative of the
10 veterinary drug distributor.

11 Sec. 16. To enable the establishment of distribution of
12 veterinary legend drugs in this state, the department may issue a
13 provisional license on or before July 1, 2009, to any applicant who
14 meets the following conditions:

15 (1) The applicant has not been found to have committed
16 any of the acts or offenses described in section 18 of this act;

17 (2) The applicant has established written policies and
18 procedures as required by section 15 of this act; and

19 (3) The applicant has paid a fee of five hundred dollars.

20 Sec. 17. The department may waive requirements under
21 sections 13 to 16 of this act upon proof satisfactory to
22 the department that such requirements are duplicative of other
23 requirements of Nebraska laws, rules, or regulations and that the
24 granting of such waiver will not endanger the public safety.

25 Sec. 18. (1) A veterinary drug distributor license may
26 be denied, refused renewal, suspended, limited, or revoked by the
27 Director of Public Health if he or she finds that the applicant

1 or licensee; the designated representative; the owner if a sole
2 proprietorship; or any person having an interest in the applicant
3 or licensee of more than ten percent has been found to have
4 committed any of the following acts or offenses:

5 (a) Violation of the Veterinary Drug Distribution
6 Licensing Act or the rules and regulations adopted and promulgated
7 under the act;

8 (b) Conviction of a misdemeanor or felony under state
9 law, federal law, or the law of another jurisdiction which, if
10 committed within this state, would have constituted a misdemeanor
11 or felony under state law and which has a rational connection with
12 the person's capacity to distribute veterinary legend drugs;

13 (c) Unprofessional conduct under the Uniform
14 Credentialing Act;

15 (d) Active addiction as defined in section 38-106;

16 (e) Permitting, aiding, or abetting veterinary drug
17 distribution or the performance of activities requiring a license
18 under the Veterinary Drug Distribution Licensing Act by a person
19 not licensed under the Veterinary Drug Distribution Licensing Act;

20 (f) Having had his or her credential denied, refused
21 renewal, limited, suspended, or revoked or having had such
22 credential disciplined in any other manner by another jurisdiction
23 relating to the performance of veterinary drug distribution;

24 (g) Performing veterinary drug distribution without a
25 valid license or in contravention of any limitation placed upon the
26 license; or

27 (h) Fraud, forgery, or misrepresentation of material

1 facts in procuring or attempting to procure a license under the
2 Veterinary Drug Distribution Licensing Act.

3 (2) The department shall issue or renew a license to any
4 applicant that satisfies the requirements for licensure or license
5 renewal under the Veterinary Drug Distribution Licensing Act.

6 Sec. 19. (1) An applicant for an initial or renewal
7 license under the Veterinary Drug Distribution Licensing Act shall
8 pay a license fee as provided in this section.

9 (2) License fees shall include (a) a base fee of fifty
10 dollars and (b) an additional fee of not more than five hundred
11 dollars based on variable costs to the department of inspections
12 and of receiving and investigating complaints, other similar direct
13 and indirect costs, and other costs of administering the act as
14 determined by the department. If an application under the act is
15 denied, the license fee shall be returned to the applicant, except
16 that the department may retain up to twenty-five dollars as an
17 administrative fee and may retain the entire license fee if an
18 inspection has been completed prior to such denial.

19 (3) The department shall also collect a fee established
20 by the department, not to exceed the actual cost to the department,
21 for reinstatement of a license that has lapsed or has been
22 suspended or revoked. The department shall collect a fee of ten
23 dollars for a duplicate original license.

24 (4) The department shall remit all license fees collected
25 under the act to the State Treasurer for credit to the Health and
26 Human Services Cash Fund. License fees collected under this section
27 shall only be used for activities related to the licensure of

1 veterinary drug distributors.

2 Sec. 20. A veterinary drug distributor license shall
3 expire on July 1 of each odd-numbered year and may be renewed.
4 The license shall not be transferable. The department shall mail
5 an application for renewal to each licensee not later than May 15
6 of the year the license expires. If an application for renewal is
7 received from the licensee after July 1, the department may impose
8 a late fee and shall refuse to issue the license until such late
9 fee and renewal fee are paid. Failure to receive an application for
10 renewal shall not relieve the licensee from the late fee imposed by
11 this section.

12 Sec. 21. (1) Except as otherwise provided in section 16
13 of this act, each veterinary drug distributor transacting commerce
14 in this state shall be inspected by the department prior to the
15 issuance of an initial or renewal license by the department under
16 the Veterinary Drug Distribution Licensing Act.

17 (2) The department may provide in rules and regulations
18 for the inspection of any veterinary drug distributor licensed in
19 this state in such manner and at such times as the department
20 determines. As part of any such inspection, the department may
21 require an analysis of suspected veterinary legend drugs to
22 determine authenticity.

23 (3) For applicants not located in this state, the
24 department may accept an inspection which was accepted for
25 licensure by another state in which the applicant is licensed
26 or by a nationally-recognized accreditation program in lieu of an
27 inspection by the department under this section.

1 (4) The department may establish and collect fees for
2 inspection activities conducted under this section. Such fees
3 shall not exceed the department's actual cost for such inspection
4 activities.

5 (5) The department may adopt and promulgate rules
6 and regulations which permit the use of alternative methods
7 for assessing a licensee's compliance with the Veterinary Drug
8 Distribution Licensing Act and the rules and regulations by a
9 veterinary drug distributor.

10 Sec. 22. (1) A veterinary drug distributor transacting
11 commerce in this state shall establish and maintain accurate
12 records of all transactions regarding the receipt and distribution
13 or other disposition of veterinary legend drugs as provided in the
14 Veterinary Drug Distribution Licensing Act.

15 (2) All records of receipt, distribution, or other
16 disposal of veterinary legend drugs shall be available to the
17 department upon request for inspection, copying, verifying, or
18 other proper use.

19 (3) If a veterinary drug distributor is authorized by
20 the department to maintain records at a central location, such
21 records shall be made available for authorized inspections within
22 forty-eight hours.

23 (4) Records kept at a central location that can be
24 retrieved by computer or other electronic means shall be readily
25 available for authorized inspection during the inspection period.

26 Sec. 23. A veterinary drug distributor may distribute
27 veterinary legend drugs to:

1 (1) A licensed veterinarian or to another veterinary drug
2 distributor subject to the requirements of section 22 of this act;
3 and

4 (2) A layperson responsible for the control of an animal
5 if:

6 (a) A licensed veterinarian has issued, prior to such
7 distribution, a veterinary drug order for the drug in the course of
8 an existing, valid veterinarian-client-patient relationship;

9 (b) At the time the veterinary legend drug leaves
10 the licensed location of the veterinary drug distributor, the
11 distributor possesses a copy of the veterinary drug order for the
12 veterinary legend drug;

13 (c) The original order is retained on the premises of the
14 veterinary drug distributor or an authorized central location for
15 three years after the date of the last transaction affecting the
16 order and includes the following information:

- 17 (i) Client name;
- 18 (ii) Veterinarian name;
- 19 (iii) Drug sold or delivered;
- 20 (iv) Quantity of the drug;
- 21 (v) Date of issue of order; and
- 22 (vi) Expiration date of order;

23 (d) All veterinary legend drugs distributed on the order
24 of a licensed veterinarian are sold in the original, unbroken
25 manufacturer's containers; and

26 (e) The drugs, once distributed, are not returned to the
27 veterinary drug distributor for resale or redistribution.

1 Nothing contained in Nebraska statutes governing the
2 practice of pharmacy shall be construed to prohibit a veterinary
3 drug distributor from selling or otherwise distributing a
4 veterinary legend drug pursuant to a veterinary drug order
5 by a veterinarian licensed in this state and, when a valid
6 veterinarian-client-patient relationship exists, to the layman
7 responsible for the control of the animal.

8 (3) If all federal labeling requirements are met,
9 labeling provisions of Nebraska laws governing the practice of
10 pharmacy shall not apply to veterinary legend drugs distributed
11 pursuant to the Veterinary Drug Distribution Licensing Act.

12 Sec. 24. A veterinary drug distributor shall not:

13 (1) Operate from a place of residence;

14 (2) Possess, sell, purchase, trade, or otherwise furnish
15 controlled substances; and

16 (3) Possess, sell, purchase, trade, or otherwise furnish
17 human legend drugs.

18 Sec. 25. The department, the Attorney General, or any
19 county attorney may institute an action in the name of the state
20 for an injunction or other process against any person to restrain
21 or prevent any violation of the Veterinary Drug Distribution
22 Licensing Act or any rules and regulations adopted and promulgated
23 under the act.

24 Sec. 26. It is unlawful for any person to commit or to
25 permit, cause, aid, or abet the commission of any of the following
26 acts in this state:

27 (1) Any violation of the Veterinary Drug Distribution

1 Licensing Act or rules and regulations adopted and promulgated
2 under the act;

3 (2) Providing the department, any of its representatives,
4 or any federal official with false or fraudulent records or making
5 false or fraudulent statements regarding any matter under the act;

6 (3) Obtaining or attempting to obtain a veterinary legend
7 drug by fraud, deceit, or misrepresentation or engaging in the
8 intentional misrepresentation or fraud in the distribution of a
9 veterinary legend drug;

10 (4) Except for the distribution by manufacturers of
11 a veterinary legend drug that has been delivered into commerce
12 pursuant to an application approved under federal law by the
13 federal Food and Drug Administration, the manufacture, repackaging,
14 sale, transfer, delivery, holding, or offering for sale of
15 any veterinary legend drug that is adulterated, misbranded,
16 counterfeit, suspected of being counterfeit, or otherwise rendered
17 unfit for distribution;

18 (5) Except for the wholesale distribution by
19 manufacturers of a veterinary legend drug that has been
20 delivered into commerce pursuant to an application approved under
21 federal law by the federal Food and Drug Administration, the
22 adulteration, misbranding, or counterfeiting of any veterinary
23 legend drug;

24 (6) The deliberate receipt of any veterinary legend drug
25 that is adulterated, misbranded, stolen, obtained by fraud or
26 deceit, counterfeit, or suspected of being counterfeit and the
27 delivery or proffered delivery of such drug for pay or otherwise;

1 (7) The alteration, mutilation, destruction,
2 obliteration, or removal of the whole or any part of the labeling
3 of a veterinary legend drug or the commission of any other act with
4 respect to a veterinary legend drug that results in the veterinary
5 legend drug being misbranded;

6 (8) For purposes of the Veterinary Drug Distribution
7 Licensing Act, the manufacture, repackaging, sale, transfer,
8 delivery, holding, possessing or offering for sale, trade, or any
9 other form of dissemination, any controlled substance; and

10 (9) Prohibiting or otherwise impeding access, during
11 normal business hours, to any paper or electronic records or any
12 premises, facility, area, or location to which access is authorized
13 by the act.

14 Sec. 27. (1) Upon issuance of a final disciplinary action
15 against a person who knowingly and intentionally violates any
16 provision of section 26 of this act other than as provided in
17 subsection (2) of this section, the department shall assess a fine
18 of one thousand dollars against such person. For each subsequent
19 final disciplinary action for violation of such section issued by
20 the department against such person, the department shall assess a
21 fine of one thousand dollars plus one thousand dollars for each
22 final disciplinary action for violation of such section previously
23 issued against such person, not to exceed ten thousand dollars.

24 (2) Upon issuance of a final disciplinary action against
25 a person who fails to provide an authorized person the right of
26 entry provided in section 26 of this act, the department shall
27 assess a fine of five hundred dollars against such person. For

1 each subsequent final disciplinary action for such failure issued
2 against such person, the department shall assess a fine equal to
3 one thousand dollars times the number of such disciplinary actions,
4 not to exceed ten thousand dollars.

5 (3) All fines collected under this section shall be
6 remitted to the State Treasurer for distribution in accordance with
7 Article VII, section 5, of the Constitution of Nebraska.

8 Sec. 28. (1) If the department finds there is a
9 reasonable probability that (a) a veterinary drug distributor
10 has knowingly and intentionally falsified documents relevant to the
11 purchase, sale, or distribution of veterinary legend drugs or has
12 sold, distributed, transferred, manufactured, repackaged, handled,
13 or held a counterfeit veterinary legend drug and (b) such drug
14 could cause serious, adverse health consequences or death, the
15 department may issue an order to immediately cease distribution of
16 such drug.

17 (2) Persons subject to any order issued by the department
18 under this section shall be provided with notice and an opportunity
19 for an informal hearing to be held not later than thirty days after
20 the date the order was issued. If the department determines, after
21 such hearing, that inadequate grounds exist to support the actions
22 required by the order, the department shall vacate the order.

23 Sec. 29. The department may adopt and promulgate rules
24 and regulations to carry out the Veterinary Drug Distribution
25 Licensing Act.

26 Sec. 30. Any person who knowingly and intentionally
27 engages in distribution of veterinary legend drugs in this state

- 1 in violation of the Veterinary Drug Distribution Licensing Act is
- 2 guilty of a Class III felony.